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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------|---|----------------------|-----------------------|------------------|
| 10/685,282 | 10/14/2003 | Ying Sun | J&J5043USCIP1 | 4927 |
| 27777 PHILIP S. JOH | 7590 12/14/2001 NSON | 1 | EXAMINER | |
| JOHNSON & JOHNSON | | | MENDEZ, MANUEL A | |
| - | N & JOHNSON PLAZ VICK, NJ 08933-7003 | A | ART UNIT PAPER NUMBER | |
| | | | 3763 | |
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| | | | MAIL DATE | DELIVERY MODE |
| | | | 12/14/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | -MN/ |
|---|--|---|--------------|
| , | Application No. | Applicant(s) | , = • |
| Office Assistant Community | 10/685,282 | SUN ET AL. | |
| Office Action Summary | Examiner | Art Unit | |
| | Manuel Mendez | 3763 | |
| The MAILING DATE of this communication app Period for Reply | pears on the cover sheet with th | e correspondence addre | ?SS |
| A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICAT 36(a). In no event, however, may a reply b will apply and will expire SIX (6) MONTHS for cause the application to become ABANDO | ION. e timely filed rom the mailing date of this comm DNED (35 U.S.C. § 133). | |
| Status | • | | |
| 1) Responsive to communication(s) filed on <u>02 C</u> | <u> October 2007</u> . | | |
| 2a) ☐ This action is FINAL . 2b) ☑ This | action is non-final. | | |
| 3) Since this application is in condition for allowa closed in accordance with the practice under E | • | • | erits is |
| Disposition of Claims | | | |
| 4)⊠ Claim(s) <u>3-14 and 16-25</u> is/are pending in the | application. | | |
| 4a) Of the above claim(s) is/are withdraw | wn from consideration. | | |
| 5) Claim(s) is/are allowed. | | | |
| 6)⊠ Claim(s) <u>3-14 and 16-25</u> is/are rejected. | | | |
| 7) Claim(s) is/are objected to. | | | |
| 8) Claim(s) are subject to restriction and/o | r election requirement. | | |
| Application Papers | | | |
| 9) The specification is objected to by the Examine | er. | | |
| 10) The drawing(s) filed on is/are: a) acc | epted or b) objected to by th | e Examiner. | |
| Applicant may not request that any objection to the | drawing(s) be held in abeyance. | See 37 CFR 1.85(a). | |
| Replacement drawing sheet(s) including the correct | tion is required if the drawing(s) is | objected to. See 37 CFR ⁴ | 1.121(d). |
| 11) The oath or declaration is objected to by the Ex | caminer. Note the attached Off | ice Action or form PTO- | 152. |
| Priority under 35 U.S.C. § 119 | | | |
| 12) Acknowledgment is made of a claim for foreign | priority under 35 U.S.C. § 119 | (a)-(d) or (f). | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | |
| Certified copies of the priority document | s have been received. | | |
| Certified copies of the priority document | s have been received in Applic | ation No | |
| 3. Copies of the certified copies of the prior | • | ived in this National Sta | ige |
| application from the International Bureau | , ,,, | | |
| * See the attached detailed Office action for a list | of the certified copies not rece | ived. | |
| Attachment(s) | | | |
| Notice of References Cited (PTO-892) | 4) Interview Summ | | |
| 2) | Paper No(s)/Mai 5) Notice of Informa | al Patent Application | |
| Paper No(s)/Mail Date <u>10/02/2007</u> . | 6) Other: | ÷ • | |

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DETAILED ACTION

During the personal interview held on August 1, 2007, the parties agreed that the prior art of record does not disclose or suggest a patch wherein both, the first electrode and the second electrode are <u>in ionic communication with the same carrier</u>. Furthermore, the parties agreed that the patch disclosed by Gross et al. is a passive patch (see column 2, lines 3-5 of Gross et al.) that does not employ an electric potential as a driving force (see column 1, lines 8-13), and therefore, can not anticipate or suggest the subject matter disclosed in claim 1 of this application.

Despite the conclusions reached during the interview, the last search conducted by the examiner of record located prior art that is considered very relevant to the prosecution of this application. Accordingly, the following rejections are presented in order to expedite the prosecution of this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3-14 and 16-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fahim in view of Crisp et al., and in further view of [Sage et al. (U.S. Patent No. 5,935,598), Joshi, Muller et al. or Phipps], in further view

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of [Ledger et al., Crawford et al., or EP 0337642], in further view of [Gross et al. or Untereker et al.], and in further view of Lahamas et al.

The Fahim patent discloses a method of treating acne on the skin, the method comprising applying to the skin electrochemically generated zinc ions.

More specifically, in columns 3, lines 9-17, the specification states:

Insofar as known prior to the present discovery, it was not known that a combination of zinc ions and 10 ascorbic acid would reduce the rate at which sebum is secreted and that if it was applied with ultrasonic vibrations that it would stimulate the production of collagen in the treatment of acne scars. Nor was it known that a combination of zinc ions and ascorbic acid could give 15 rise to a synergistic combination useful in killing the normal microflora found in the pilosebaceous ducts.

The Fahim patent does not disclose the use of an apparatus having an anode comprising of zinc. However, the application of zinc ions using a device having an anode comprising zinc is conventional in the art as evidenced by the teachings of Crisp et al. The Crisp et al., patent discloses an electrolytic device and teaches the use of an anode comprising zinc.

Based on the teachings of Crisp et al., for a person of ordinary skill in the art, modifying the teachings of the Fahim patent with the use of the electrolytic apparatus of Crisp et al., would have been considered obvious in view of the conventionality of the use of electrolytic apparatuses to treat skin with zinc ions.

Additionally, Sage et al., patent does not specifically disclose a power source producing a current density of less than .1 mA/cm(2). However, power

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sources with said output are conventional in the art as evidenced by Muller et al. The teachings of Muller et al., clearly demonstrate that the use of electrical generators having current densities between .05 and .25 is well known in the art. Accordingly, for a person of ordinary skill in the art, it would be obvious to modify the power supply of Sage et al. with a power supply capable of outputting current densities within the range in question. Conclusively, such substitution would have been considered an obvious design alternative.

The Ledger et al., Phipps, Crawford et al., or EP 0337642, individually or in combination at least suggest the conventionality of designing an apparatus wherein both the first conductive electrode and the second conductive electrode are in ionic communication with the carrier. Accordingly, for a person of ordinary skill in the art, modifying the apparatus disclosed by Sage et al., with a first conductive electrode and a second conductive electrode in ionic communication would have been considered obvious in view of the proven conventionality of this enhancement.

In relation to applicant's arguments concerning the phrase "ionic or electrical communication", the **Gross et al.** patent discloses a transdermal drug delivery apparatus having a power source, a cathode, and anode, and a carrier. Importantly, this patent demonstrates the conventionality of designing a patch wherein both the first conductive electrode and the second electrode are in ionic communication with the same carrier.

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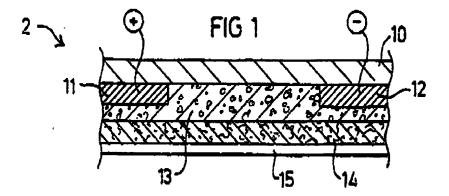


Figure 1 above shows a patch having an anode and a cathode in ionic communication with the same carrier and with no insulator between them.

Accordingly, for a person of ordinary skill in the art, modifying the apparatus disclosed by Crisp et al., or Sage et al. (U.S. Patent No. 5,935,598) with the removal of the insulator located between electrodes, as taught by Gross et al., would have been considered obvious in view of the proven conventionality of this enhancement.

Concerning the term "electrochemically", iontophoresis apparatuses that generate zinc ions electrochemically are well known in the art as evidenced by the teachings of Untereker et al. This patent discloses an iontophoretic apparatus having a zinc anode and electrochemically produced ions. Moreover, the specification of this patent discloses the problem of hot spots when the cathode and anode are not compartmentalized, or in direct ionic communication. Interestingly, the comparison of compartmentalized apparatuses with non-

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compartmentalized apparatuses demonstrates that both designs are conventional in the art.

Based on the above observations, for a person of ordinary skill in the art, modifying the apparatuses disclosed by Crisp et al. or Sage et al., U.S. Patent No. 5,935,598, with a zinc anode and the capability of generating electrochemically produced ions would have been considered an obvious design choice.

Finally, in relation to the use of a design wherein the first electrode and the second electrode are in ionic communication with the same carrier, the

Lahamas et al. patent discloses a method for preventing or treating skin damage which comprises applying to the skin a cosmetic or pharmaceutical composition containing an effective amount of a cosmetically or pharmaceutically acceptable compound capable of acting as an electron donor, simultaneously or substantially simultaneously with the application to the same skin of a composition containing an effective amount of a cosmetically or pharmaceutically acceptable compound capable of acting as an electron acceptor, whereby an exchange of electrons between the electron donor and electron acceptor results in generation of an electrical current on the skin in the absence of an external source of electricity.

Lahamas et al. discloses designs wherein the donor and acceptor are each contained in separate carriers or together in the same carrier.

Accordingly, for a person of ordinary skill in the art, modifying the apparatus disclosed by Fahim with a design wherein both electrodes are positioned within

the same carrier, as taught by Lahamas et al., would have been considered obvious in view of the proven conventionality of this particular patch design.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 571-272-4962. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Manuel Mendez Primary Examiner

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